

DEC 17 2010

#702, Kolon Science Valley 2nd, 811
Guro-Dong, Guro-Gu, Seoul, 152-050 Korea
Tel : +82 2 850 3500 / Fax : +82 2 850 3535

510(k) Summary

K101563

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92(c).

Date: October 19, 2010

1. Company and Correspondent making the submission:

	Company
Name	Jeil Medical Corporation
Address	#702, kolon science valley 2nd 811, Guro-Dong, Guro-Gu Seoul, Republic of Korea 152-050
Phone	+82 2 850-3500
Fax	+82 2 850-3535
Contact	Jieun Kim

2. Device:

Proprietary Name – SMARTO

Common Name – Surgical motor unit for surgery

Classification Name -- Instrument, Surgical orthopedic, DC-powered motor and accessory/attachment

3. Predicate Device:

The OSTEOMED "B" power system and accessories, K933101

4. Classifications Names & Citations:

KIJ, Unclassified

5. Description:

The SMARTO is a sterile battery powered screwdriver. The device includes a DC motor, battery, switch and holder for the rotation attachment. It is disposable.

6. Indication for use:

The SMARTO is used to drive screws, and drilling in conjunction with craniofacial (does not include maxillofacial applications), craniotomies, hand, foot, wrist and extremity reconstruction surgical procedures. It is supplied sterile and is for single use only.



7. Review:

The SMARTO is substantially equivalent to the commercially available predicate products based on the intended use, technology, energy source, claims, and the material composition employed. Accordingly we can claim the substantially equivalence of the SMARTO to predicate devices.

8. Summary of performance testing:

Bench testing has been performed on mechanical properties; motor speed, torque. The results of Bench test show the safety and effectiveness of the SMARTO.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Jeil Medical Corporation concludes that the SMARTO are safe and effective and substantially equivalent to predicate devices as described herein.

END



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

DEC 17 2010

Jeil Medical Corporation
% GS Standard Co., Ltd.
Kim Seong Nam
1006 Digital 2 Cha Valley
Byucksan, Gasan-Seoul
Republic of Korea

Re: K101563

Trade/Device Name: SMARTO
Regulation Number: 21 CFR 878.4820
Regulation Name: Surgical instrument motors and accessories/attachment
Regulatory Class: Class I
Product Code: KIJ
Dated: December 05, 2010
Received: December 08, 2010

Dear Kim Seong Nam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

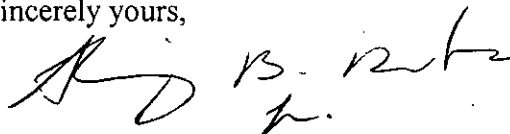
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'M. N. Melkerson', is written over the typed name.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Submission – SMARTO

510(k) Number K101563

Device Name: SMARTO

Indication for use:

The SMARTO is intended for use in driving screws, and drilling in conjunction with craniofacial (does not include oromaxillofacial applications), craniotomies, hand, foot, wrist and extremity reconstruction surgical procedures. It is supplied sterile and single use only.

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Prescription Use _____ OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Orden for man
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101563